

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** COHORT\_SELECTION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Cohort Selection**

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	30 JUN 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/11/2020
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**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

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**Demography**

1.	Subject ID	[12261094]
2.	Birth Date:	(b) (6) 1989
3.	Sex:	FEMALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/11/2020
2.	Erroneous Visit	

**Header Text:** C4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 30-Jul-2020 21:27**Site No:** 1226**Subject No:** 12261094**Generated By:** (b) (4)**Form:** INCLUSION/EXCLUSION CRITERIA**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[eCRF Audit Trail History](#)

Study eligibility requires subjects to meet all inclusion criteria (YES) and Not meet exclusion criteria (NO).

**Inclusion Criteria**

1.a	Inclusion Number:	1
	Criterion Description:	Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN01A00
1.b	Inclusion Number:	2
	Criterion Description:	Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN02A00
1.c	Inclusion Number:	3
	Criterion Description:	Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN03A00
1.d	Inclusion Number:	4
	Criterion Description:	Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol
	Criterion met?	YES
	Criterion ID: (For Pfizer use only)	IN04A00

**Exclusion Criteria**

2.a	Exclusion Number:	1
	Criterion Description:	Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX01A00

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

2.b	Exclusion Number:	2
	Criterion Description:	Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX02A00
2.c	Exclusion Number:	3
	Criterion Description:	History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg. anaphylaxis) to any component of the study intervention(s)
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX03A00
2.d	Exclusion Number:	4
	Criterion Description:	Receipt of medications intended to prevent COVID-19
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX04A00
2.e	Exclusion Number:	8
	Criterion Description:	Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX08A00
2.f	Exclusion Number:	10
	Criterion Description:	Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX10A00
2.g	Exclusion Number:	11
	Criterion Description:	Women who are pregnant or breastfeeding
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX11A00

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

2.h	Exclusion Number:	12
	Criterion Description:	Previous vaccination with any coronavirus vaccine
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX12A00
2.i	Exclusion Number:	13
	Criterion Description:	Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX13A01
2.j	Exclusion Number:	15
	Criterion Description:	Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX14A01
2.k	Exclusion Number:	16
	Criterion Description:	Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX15A01
2.l	Exclusion Number:	17
	Criterion Description:	Previous participation in other studies involving study intervention containing lipid nanoparticles
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX16A01
2 m	Exclusion Number:	22
	Criterion Description:	Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members
	Criterion met?	NO
	Criterion ID: (For Pfizer use only)	EX21A01

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/11/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	Sep/UNK/1995
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Allergy to dipyrone]
	Start Date:	Jul/UNK/2013
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Nephrolithiasis]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/11/2020
2.	Weight:	[81.0]
3.	Unit:	kg
4.	Height:	[158.6]
5.	Unit:	cm
6.	Body Mass Index:	[32.2]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.5]
	Unit:	C
	Temperature Location:	FOREHEAD

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/11/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/11/2020
2.	Randomization Number:	[46257]
3.	Randomization Group:	[ ]

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5H8Y]
5.b	Sample ID	[BP5H8H]
5.c	Sample ID	[BP5H8X]
5.d	Sample ID	[BLCTF7]
5.e	Sample ID	[BLCTF6]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP5H74]
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/11/2020 13:48
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/1/2020
2.	Erroneous Visit	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/17/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Aug/17/2020
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

2.g	Symptom:	NEW OR WORSENERD MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/1/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/1/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP9DRG]
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/1/2020 14:15
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/30/2020
2.	Erroneous Visit	



Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

2.h	Symptom:	NEW OR WORSENERD JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/30/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP7XM6]
5.b	Sample ID	[BLC0HT]
5.c	Sample ID	[BLC0HS]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET  
Sep/22/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/22/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Sep/22/2020

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Sep/22/2020
2.	Date of First Symptom Started:	Sep/16/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Sep/29/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	YES

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Sep/22/2020

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>
3.	Specimen Collection Location:	Not Applicable _____	<a href="#">Comments</a>
4.	Assay Code and Description:	Not Applicable _____	<a href="#">Comments</a>
5.	Device Type:	Not Applicable _____	<a href="#">Comments</a>
6.	Trade Name:	Not Applicable _____	<a href="#">Comments</a>
7.	Test Result:	Not Applicable _____	<a href="#">Comments</a>
8.	Comments/Findings/Details:	Not Applicable _____ [ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[The nasal swab was performed on site. The barcode is attached on "SWAB PFE" item.]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
Sep/22/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP7X7C]
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION  
Sep/22/2020

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]
----	-------------------------------------	-----

**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO
----	--	----

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Respiratory Treatment**

1.	What is the treatment Identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Concomitant Non-drug Treatment Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
3.	Treatment:	Not Applicable _____	<a href="#">Comments</a>
4.	Treatment:	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	2

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Category of Clinical Event	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE  
Sep/22/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
2.	Subcategory of Clinical Event:	Not Applicable _____	<a href="#">Comments</a>
3.	Was a diagnosis obtained?	Not Applicable _____	<a href="#">Comments</a>
4.	Toxicity Grade:	Not Applicable _____	<a href="#">Comments</a>



Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 30-Jul-2020 21:27

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)  
[Form Comments](#)  
[eCRF Audit Trail History](#)

**Lab Chemistry Details**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

5 f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 30-Jul-2020 21:28

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	
					Not Applicable	Not Applicable	Not Applicable	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Laboratory Data Hematology**

1.	Lab Panel:	Not Applicable _____	<a href="#">Comments</a>
2.	Laboratory Name and Address	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	Collection Date:	Not Applicable _____ //	<a href="#">Comments</a>
4.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

5 f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

5.h	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.i	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

5.j	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Lymphocytes_PX611	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date:	Vital Signs Details			Form Instance
1.	Sep/22/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	107	67	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Vital Signs**

1.	Date:	Sep/22/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[107]
	Diastolic:	[67]
	Respiratory Rate in respirations/minute:	[16]
	Heart Rate in beats/minute:	[79]

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date:	Vital Signs Details		Form Instance
1.	Sep/22/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	97.0	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Vital Signs**

1.	Date:	Sep/22/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[97.0]



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Oxygenation Parameters**

1.	Date Time of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Arterial Blood Gases PaO2 (mmHg):	Not Applicable _____ [ ]	<a href="#">Comments</a>
3.	FiO2 (Fraction of Inhaled Oxygen):	Not Applicable _____ [ ]	<a href="#">Comments</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Concomitant Medications**

1.	What is the medication identifier?	Not Applicable _____ [ ]	<a href="#">Comments</a>
2.	Category:	Not Applicable _____	<a href="#">Comments</a>
3.	Concomitant Medications Pre-specified:	Not Applicable _____	<a href="#">Comments</a>
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	Not Applicable _____ [ ]	<a href="#">Comments</a>
5.	Start Date:	Not Applicable _____ //	<a href="#">Comments</a>
6.	Ongoing?	Not Applicable _____	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Imaging**

1.	Date of Assessment:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Location of Assessment:	Not Applicable _____	<a href="#">Comments</a>
3.	Type of Imaging Exam:	Not Applicable _____	<a href="#">Comments</a>
4.	Assessment:	Not Applicable _____	<a href="#">Comments</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET  
Dec/15/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/15/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_B
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Dec/15/2020
2.	Date of First Symptom Started:	Dec/9/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/15/2020

**Symptoms**

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	NO
4.h	Symptoms:	DIARRHEA
	Was symptom present?	YES
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Symptoms - Other**

5.	Symptoms - Other Text:	[ ]
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN  
Dec/15/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Not Applicable _____ //	<a href="#">Comments</a>
2.	Specimen Type:	Not Applicable _____	<a href="#">Comments</a>
3.	Specimen Collection Location:	Not Applicable _____	<a href="#">Comments</a>
4.	Assay Code and Description:	Not Applicable _____	<a href="#">Comments</a>
5.	Device Type:	Not Applicable _____	<a href="#">Comments</a>
6.	Trade Name:	Not Applicable _____	<a href="#">Comments</a>
7.	Test Result:	Not Applicable _____	<a href="#">Comments</a>
8.	Comments/Findings/Details:	Not Applicable _____ [ ]	<a href="#">Comments</a>
9.	Trade Name Other, Specify:	Not Applicable _____ [ ]	<a href="#">Comments</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF  
Dec/15/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Dec/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[RW90986]
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[SELF SWAB]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION  
Dec/15/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda**Subject No:** 12261094**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Form Comments](#)  
[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST	
	Occurrence of Visits or Contacts:	NO	<a href="#">Comments</a>
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM	
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]	<a href="#">Comments</a>
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN	
	Occurrence of Visits or Contacts:	NO	<a href="#">Comments</a>
1.d	Physician or Healthcare Professional:	URGENT CARE	
	Occurrence of Visits or Contacts:	NO	<a href="#">Comments</a>
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION	
	Occurrence of Visits or Contacts:	NO	<a href="#">Comments</a>
1.f	Physician or Healthcare Professional:	OTHER	
	Occurrence of Visits or Contacts:	NO	<a href="#">Comments</a>

**Health Care Utilization Other**

2.	Other Type of Practitioner Specify:	[ ]	<a href="#">Comments</a>
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**Health Care Utilization**

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO	<a href="#">Comments</a>
----	--	----	--------------------------

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT

Dec/15/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Respiratory Treatment**

1.	What is the treatment Identifier?	[ ]
2.	Concomitant Non-drug Treatment Pre-specified:	
3.	Treatment:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** ILLNESS DETAILS  
Dec/15/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE  
Dec/15/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Illness Details**

1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test :	Result:	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
Dec/15/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Category for Lab Test	Vendor Name (DE RIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
Dec/15/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - COVID

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID  
Dec/15/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Vital Signs**

1.	Date:	//
----	-------	----

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 30-Jul-2020 21:28

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date:	Vital Signs Details		Form Instance
1.		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
Dec/15/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Vital Signs**

1.	Date:	//
----	-------	----

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS  
Dec/15/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
Dec/15/2020

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Start Date:	//
6.	Ongoing?	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** IMAGING  
Dec/15/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/11/2020

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/11/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
----	-------------------------	----------

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/11/2020

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/11/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR697H]
5.b	Sample ID	[BS2XK0]
5.c	Sample ID	[BS2XJZ]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Feb/04/2021

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/4/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_B1
----	-------------------------	----------

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Feb/04/2021

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/4/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR6867]
5.b	Sample ID	[BSCW48]
5.c	Sample ID	[BSCW47]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Unplanned Assessments**

1.	Assessments	
----	-------------	--

**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Sep/30/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]



**Header Text:** C4591001

**Visit:** Follow-Up - Unscheduled

**Form Version:** 15-Sep-2020 21:53

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Disposition - Follow-Up**

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** DATE OF VISIT - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

3.	COVID-19 Repeat Swab:	
----	-----------------------	--

**Header Text:** C4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VITAL SIGNS - TEMP

**Form Version:** 28-Mar-2021 02:28

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Vital Signs**

1.	Date:	//
----	-------	----

**Vital Signs Details**

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]



**Header Text:** C4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Feb/19/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3  Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/4/2021
----	--------------	---

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Form Comments](#)

**Inclusion Criteria Not Met**

1.	Description of Inclusion Criterion Not Met	Not Applicable
----	--	----------------

**Exclusion Criteria Met**

2.	Description of Exclusion Criterion Met	Not Applicable
----	--	----------------

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:31

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Mar/11/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Mar/11/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRGZ3L]
5.b	Sample ID	[BRXW7T]
5.c	Sample ID	[BRXW7V]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BRGZ4D]
-----	-----------	----------

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/11/2021 10:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 20-Feb-2021 02:14

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Lab Urinalysis**

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

**Lab Result**

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Electronic Sample Tracking**

1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
----	-----------	-----

**Header Text:** C4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



**Header Text:** C4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** C4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V104\_MONTH6

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** C4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** C4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Contact Outcome**

1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

**Header Text:** C4591001

**Visit:** FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

**Header Text:** C4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Worsening of Nephroli thiasis	Dec/21/2020 UNK: UNK	NO End Date Time: Jan/22/2021 UNK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	Urinary tract infection	Dec/29/2020 UNK: UNK	NO End Date Time: Jan/5/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Worsening of Nephrolithiasis]
4.	Start Date Time:	Dec/21/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Nephrolithiasis]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021006926]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)  
[eCRF Audit Trail History](#)  
[Form Audit Trail](#)

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Urinary tract infection]
4.	Start Date Time:	Dec/29/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/5/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Worsening of nephrolithiasis]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Category	Medication Error	Start Date	Is the medication error Still On going	Study Medication Errors Action	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Medication Error**

1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY  
VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication:  Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						<a href="#">Repeating Pages</a>



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Concomitant Medications**

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**Radiation Treatment**

1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

**Header Text:** C4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

1.	Transfusion Type:	
2.	Date of Transfusion:	//

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Feb/20/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** WITHDRAWAL OF CONSENT

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Withdrawal Of Consent**

1.	Withdrawal of Consent Date :	//
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**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**Death Details**

1.	Date of Collection / Notification of Death:	//
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**Cause of Death**

2.	Cause of Death Status:	
	Cause of Death:	[ ]



**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/30/2020

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	Click Here to Enable
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**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Audit Trail](#)

This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Cristiano Zerbini	Approved	Mar-12-2021 09:27:11 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

By my dated signature below, I, CristianoZerbini, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

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**Site No:** 1226

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Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
2	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

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Servicos Medicos Ltda

**Subject No:** 12261094

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
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Servicos Medicos Ltda

**Subject No:** 12261094

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
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**Form Status:** Data Complete, Frozen, Verified

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Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
6	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
7	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
8	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
9	Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1	Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

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Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
2	Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Comments  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

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Servicos Medicos Ltda

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5	Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
6	Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments  
Sep/22/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-22-2020 16:56:29 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments  
Sep/22/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1	Sep-22-2020 16:56:29 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - Comments  
Sep/22/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
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[Back to Form](#)

Item	Date	User	Comment
2	Sep-22-2020 16:56:29 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 16:56:29 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

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**Subject No:** 12261094

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1	Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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[Back to Form](#)

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

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**Subject No:** 12261094

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

**Form Version:** 30-Jul-2020 21:27

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.a	Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.c	Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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[Back to Form](#)

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[Back to Form](#)

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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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**Form Version:** 30-Jul-2020 21:27

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**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.d	Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Form Version:** 30-Jul-2020 21:27

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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[Back to Form](#)

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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**Form Version:** 30-Jul-2020 21:28

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
2	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

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**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.a	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.c	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



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[Back to Form](#)

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[Back to Form](#)

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.d	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

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**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.d	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.d	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

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**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.e	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

**Form Version:** 30-Jul-2020 21:28

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**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.e	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

**Header Text:** C4591001

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.f	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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**Form Version:** 30-Jul-2020 21:28

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**Subject No:** 12261094

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

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[Back to Form](#)

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
5.j	Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

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Sep/22/2020

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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Sep/22/2020

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Servicos Medicos Ltda

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**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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Sep/22/2020

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Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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Sep/22/2020

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 16:58:54 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

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Sep/22/2020

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Servicos Medicos Ltda

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**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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Sep/22/2020

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Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Subject No:** 12261094

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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[Back to Form](#)

Item	Date	User	Comment
3	Sep-22-2020 16:59:19 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Sep/22/2020

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 16:59:19 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable



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[Back to Form](#)

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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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[Back to Form](#)

Item	Date	User	Comment
6	Sep-22-2020 16:59:19 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

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Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

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Sep/22/2020

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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Sep/22/2020

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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[Back to Form](#)

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Sep/22/2020

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
4	Sep-22-2020 16:59:37 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Dec/15/2020

**Form Version:** 06-Jul-2020 21:54

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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Dec/15/2020

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Dec/15/2020

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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[Back to Form](#)

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[Back to Form](#)

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[Back to Form](#)

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
6	Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

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Dec/15/2020

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Servicos Medicos Ltda

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**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Dec/15/2020

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Servicos Medicos Ltda

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**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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Dec/15/2020

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

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Servicos Medicos Ltda

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**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1.a	Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
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**Form:** HEALTH CARE UTILIZATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1.b	Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
1.b	Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1.c	Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
1.c	Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1.d	Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
1.d	Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1.e	Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
1.e	Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
1.f	Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
1.f	Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
2	Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
2	Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** HEALTH CARE UTILIZATION - Comments

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
3	Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	
3	Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Unknown

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER  
VACCINATION - Comments

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Item	Date	User	Comment
Form	Mar-11-2021 11:25:54 (UTC-03:00) City of Buenos Aires	(b) (4), (b) (6)	Not Applicable

Header Text: C4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

This form requires signing by a member of each of the following signature groups:

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Cristiano Zerbini	Approved	Mar-12-2021 09:27:11 (UTC-03:00) City of Buenos Aires	BOOK	Signed

**Affidavit:**

By my dated signature below, I, CristianoZerbini, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Mar-11-2021 11:24:49 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Feb-05-2021 11:14:46 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CristianoZerbini, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Feb-05-2021 08:04:02 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Feb-03-2021 16:55:28 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**Affidavit:**

By my dated signature below, I, CristianoZerbini, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Jan-26-2021 16:37:31 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Jan-21-2021 16:04:34 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CristianoZerbini, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Dec-16-2020 17:39:00 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Nov-11-2020 21:46:21 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CristianoZerbini, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

(b) (6)	N/A	Nov-11-2020 14:07:51 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Oct-09-2020 16:11:49 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CristianoZerbini, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

(b) (6)	N/A	Sep-22-2020 16:44:36 (UTC-03:00) City of Buenos Aires		Edit - All signatures invalidated
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**Affidavit:**

N/A

Cristiano Zerbini	Approved	Sep-14-2020 16:36:06 (UTC-03:00) City of Buenos Aires	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, CristianoZerbini, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Aug-12-2020 08:12:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 30 JUN 2020	Initial Entry

*2. Select appropriate response - What cohort does the subject belong to?*

Date	Location	User	Value	Reason
Aug-12-2020 08:12:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*I. Consent Was:*

Date	Location	User	Value	Reason
Aug-12-2020 08:12:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/11/2020	Initial Entry



Header Text: C4591001

Visit: COHORT\_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Aug-12-2020 08:12:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12261094	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Aug-12-2020 08:11:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1989	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Aug-12-2020 08:12:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Aug-12-2020 08:12:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Aug-12-2020 08:12:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Aug-12-2020 08:12:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criteria</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage) <b>Criteria met?:</b> <b>Criteria ID:</b> (For Pfizer use only):	Initial Entry

I.a Inclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

I.a Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study stage)	Initial Entry

I.a Criterion met?

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

*1.a Criterion ID: (For Pfizer use only)*

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN01A00	Initial Entry

*1.b*

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> <b>Criteria</b> Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures <b>Criteria met?:</b> YES <b>Criteria ID:</b> IN02A00 <b>(For Pfizer use only)</b> :	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

**I.b Inclusion Number:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

**I.b Criterion Description:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participants who are willing and able to comply with all scheduled visits, v accination plan, laboratory tests, lifes tyle considerations, and other study p rocedures	Initial Entry

**I.b Criterion met?**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.b Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN02A00	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusi 3 on Nu mber:</b> <b>Criteria</b> Healthy participants who ar on Des e determined by medical his criptio tory, physical examination, n: and clinical judgment of the investigator to be eligible fo r inclusion in the study	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			<p>Criteria YES on met?:</p> <p>Criteria IN03A00 on ID: (For Pfizer use only):</p>	
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**I.c Inclusion Number:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

**I.c Criterion Description:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Healthy participants who are determined by medical history, physical examination, and clinical judgment of the investigator to be eligible for inclusion in the study	Initial Entry

**I.c Criterion met?**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN03A00	Initial Entry

**I.d**

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Inclusion Number:</b> 4 <b>Criterion Description:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol <b>Criterion met?:</b> YES <b>Criterion ID:</b> IN04A00 <b>(For Printer use only):</b>	Initial Entry
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

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**I.d Inclusion Number:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

**I.d Criterion Description:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Capable of giving personal signed informed consent, which includes compliance with the requirements and restrictions listed in the ICD and in this protocol	Initial Entry

**I.d Criterion met?**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.d Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> IN04A00	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclus 1 ion Nu mber:	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



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Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

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Generated Time (GMT): 29-Mar-2021 13:54

			<b>Criteria Description:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation  <b>Criteria met?:</b> NO  <b>Criteria ID:</b> EX01A00 <b>(For Pfizer use only):</b>	
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2.a Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

2.a Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Other medical or psychiatric condition incl. recent (within past year) or active suicidal ideation/behavior/lab abnormality that may increase the risk of study participation	Initial Entry

2.a Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.a Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Form Version:** 30-Jul-2020 21:27

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**Subject No:** 12261094

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**Generated Time (GMT):** 29-Mar-2021 13:54

Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX01A00	Initial Entry
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**2.b**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 2 <b>Criterion Description:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX02A00	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

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Generated Time (GMT): 29-Mar-2021 13:54

2.b Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

2.b Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV)	Initial Entry

2.b Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.b Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX02A00	Initial Entry

2.c

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			<p>Criteria NO on met?:</p> <p>Criteria EX03A00 on ID: (For Pfizer use only):</p>
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2.c Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

2.c Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> History of severe adverse reaction as associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s)	Initial Entry

2.c Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.c Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX03A00	Initial Entry

2.d

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	<b>Exclusion Number:</b> 4 <b>Criterion Description:</b> Receipt of medications intended to prevent COVID-19 <b>Criterion met?:</b> NO <b>Criterion ID:</b> EX04A00 <b>(For Pfizer use only):</b>
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2.d Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

2.d Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of medications intended to prevent COVID-19	Initial Entry

2.d Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.d Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX04A00	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion 8	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Subject No:** 12261094

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**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Buenos Aires		(b) (4), (b) (6)	<b>on Number:</b> <b>Criterion Description:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX08A00	
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

2.e Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 8	Initial Entry

2.e Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination	Initial Entry

2.e Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.e Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX08A00	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			<b>Criteria met?:</b> NO <b>Criteria on ID:</b> EX10A00 <b>(For Pfizer use only):</b>
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**2.f Exclusion Number:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 10	Initial Entry

**2.f Criterion Description:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection	Initial Entry

**2.f Criterion met?**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX10A00	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

(UTC-03:00) City of Buenos Aires		(b) (4), (b) (6)	<b>Exclusion Number:</b> <b>Criterion Description:</b> Women who are pregnant or breastfeeding <b>Criterion met?:</b> NO <b>Criterion ID:</b> ( EX11A00 <b>For Pfizer use only):</b>
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2.g Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 11	Initial Entry

2.g Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Women who are pregnant or breastfeeding	Initial Entry

2.g Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX11A00	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 12	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

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Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			<b>Criterion Description:</b> Previous vaccination with any coronavirus vaccine <b>Criterion met?:</b> NO <b>Criterion ID:</b> EX12A00 <b>(For Pfizer use only):</b>
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**2.h Exclusion Number:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12	Initial Entry

**2.h Criterion Description:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous vaccination with any coronavirus vaccine	Initial Entry

**2.h Criterion met?**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.h Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX12A00	Initial Entry

**2.i**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclusion Number:	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			<b>Criterion Description:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids <b>Criterion met?:</b> NO <b>Criterion ID: (For Pfizer use only):</b> EX13A01
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2.i Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 13	Initial Entry

2.i Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Subjects who receive immunosuppressive therapy, such as cytotoxic agents or systemic corticosteroids	Initial Entry

2.i Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.i Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX13A01	Initial Entry

2.j

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Subject No:** 12261094

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**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

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**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> 15 <b>Criteria Description:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study <b>Criteria met?:</b> NO <b>Criteria ID:</b> EX14A01 <b>(For Pfizer use only):</b>	Initial Entry
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

2.j Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 15	Initial Entry

2.j Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study	Initial Entry

2.j Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.j Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX14A01	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

2.k				
Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Exclusion Number:</b> <b>Criterion Description:</b> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation <b>Criterion met?:</b> NO <b>Criterion ID: (Former Pfizer use only):</b> EX15A01	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

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Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

2.k Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 16	Initial Entry

2.k Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation	Initial Entry

2.k Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.k Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX15A01	Initial Entry

2.l

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Exclusion 17 Number:</b> <b>Criterion Description:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles <b>Criterion met?:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			<b>Criterion ID: (For Pfizer use only):</b>	EX16A01
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**2.l Exclusion Number:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 17	Initial Entry

**2.l Criterion Description:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Previous participation in other studies involving study intervention containing lipid nanoparticles	Initial Entry

**2.l Criterion met?**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.l Criterion ID: (For Pfizer use only)**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EX16A01	Initial Entry

**2.m**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Exclus 22 ion Number:	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 30-Jul-2020 21:27

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

			<p><b>Criteria:</b> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members</p> <p><b>Criterion ID:</b> EX21A01 (For Pfizer use only)</p>	
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:27

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

2.m Exclusion Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 22	Initial Entry

2.m Criterion Description:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members	Initial Entry

2.m Criterion met?

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.m Criterion ID: (For Pfizer use only)

Date	Location	User	Value	Reason
Aug-12-2020 08:13:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EX21A01	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

I.a

Date	Location	User	Value	Reason
Aug-12-2020 08:13:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 1 <b>Medical History Term:</b> Asthma <b>Start Date:</b> Sep/UNK/1995 <b>Ongoing:</b> YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-12-2020 08:13:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-14-2020 14:11:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Aug-13-2020 17:48:46 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Carlos Linn (b) (4)	Query 2: Closed	Response satisfies query
Aug-13-2020 16:36:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	does not take any medication
Aug-13-2020 16:22:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Does not take any medication
Aug-13-2020 03:41:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Carlos Linn (b) (4)	Query 2: Opened	following prior query: except inhaled/nebulized corticosteroids which are permitted.

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Aug-12-2020 12:55:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	is he taking systemic corticosteroids?
Aug-12-2020 08:13:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Asthma	Initial Entry

**I.a Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/UNK/1995	Initial Entry

**I.a Ongoing:**

Date	Location	User	Value	Reason
Aug-12-2020 08:13:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.b**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 2 <b>Medical History Term:</b> Allergy to dipyrone <b>Start Date:</b> Jul/UNK/2013 <b>Ongoing:</b> YES	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

**I.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Allergy to dipyrone	Initial Entry

**I.b Start Date:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/UNK/2013	Initial Entry

**I.b Ongoing:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Jan-07-2021 10:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 3 <b>Medical History Term:</b> Nephrolithiasis <b>Start Date:</b> UNK/UNK/2016 <b>Ongoing:</b> YES	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

***I.c Line/MH Number:***

Date	Location	User	Value	Reason
Jan-07-2021 10:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

***I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Jan-07-2021 10:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nephrolithiasis	Initial Entry

***I.c Start Date:***

Date	Location	User	Value	Reason
Jan-07-2021 10:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

***I.c Ongoing:***

Date	Location	User	Value	Reason
Jan-07-2021 10:05:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 81.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 158.6	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 32.2	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 30-Jul-2020 21:28

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

7.a

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.5 <b>Temperature Unit:</b> C <b>Temperature Location::</b> FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-12-2020 08:14:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

			<b>d Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Aug-12-2020 08:14:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 46257	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 08:16:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-12-2020 08:16:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-12-2020 08:16:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 08:16:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-12-2020 08:16:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/11/2020	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Aug-14-2020 17:25:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Closed	Response satisfies query
Aug-14-2020 09:58:06 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Buenos Aires		(b) (4), (b) (6)		
Aug-14-2020 05:53:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Katherine Liao (b) (4)	Query 1: Opened	GPD CLIN: Please confirm if all sample IDs are documented for blood draw for immunogenicity as only 3 of the expected 5 sample IDs/aliquots are reported. Please provide comment for reason or update all sample IDs as applicable.

5.a

Date	Location	User	Value	Reason
Aug-12-2020 08:16:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP5H8Y</b>	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 08:16:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5H8Y	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-12-2020 08:17:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP5H8H</b>	Transcription Error
Aug-12-2020 08:16:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BP5H8Y</b>	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 08:17:27 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5H8H	Transcription Error
Aug-12-2020 08:16:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5H8Y	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-12-2020 08:17:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5H8X	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-12-2020 08:17:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5H8X	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-14-2020 09:57:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLCTF7	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-14-2020 09:57:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCTF7	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-14-2020 09:57:59 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Buenos Aires

(b) (4), (b) (6)

**Sample ID:** BLCTF6

*5.e Sample ID*

Date	Location	User	Value	Reason
Aug-14-2020 09:57:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLCTF6	Initial Entry



Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Aug-12-2020 08:17:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Aug-12-2020 08:17:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Aug-12-2020 08:17:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-12-2020 08:17:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-12-2020 08:17:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-12-2020 08:17:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP5H74	Initial Entry

**5.a Sample ID**

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Aug-12-2020 08:17:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP5H74	Initial Entry

Header Text: C4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/11/2020 13:48	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**7. Route:**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Aug-12-2020 08:15:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** C4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Aug-12-2020 08:15:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E-DIAR Y COLLECTED FOR THIS SUBJE CT	Initial Entry

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Sep-01-2020 16:30:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FATIGUE	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</p> <p>YES Ongoing ?</p> <p>NO</p> <p>Stop Date:</p> <p>Aug /17/ 2020</p>	
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2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing? NO Stop Date: Aug/17/2020	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> HEADACHE	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			<p>Were fever or systemic symptoms present on the last day the Subject Diary was completed?</p> <p>YES Ongoing ?</p> <p>NO</p> <p>Stop Date:</p> <p>Aug /17/ 2020</p>	
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2.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Ongoing? NO Stop Date: Aug/17/2020	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> CH IL LS	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: VO MIT ING  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE ED MUS CLE PAI N  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was compl eted?:</b> NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was complet ed?:</b> NO	Initial Entry

090177e196ae404f\Final\On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT PA IN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Injection Site Reaction:: RE DN ESS  Were injection site reaction NO s present on the last day the Subject Diary was complete d?:	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) ( )	<b>Data Entry:</b> REDNESS	Initial Entry
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5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) ( )	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) ( )	<b>Data Entry:</b> Injection Site Reaction:: SWE LLI NG  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) ( )	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) ( )	<b>Data Entry:</b> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) ( )	<b>Data Entry:</b> Injection Site Reaction: PAIN AT INJE	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:30

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

			CTION SITE	
			Were injection site reac tions present on the last day the Subject Diary was completed?:	NO

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 36.6 <b>Temperature Unit:</b> C <b>Temperature Location::</b> FOREHEAD	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.6	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Sep-01-2020 16:33:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FOREHEAD	Initial Entry
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

			<b>d Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	
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**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-01-2020 16:33:38 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Sep-01-2020 17:30:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-01-2020 17:30:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-01-2020 17:30:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 17:30:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 17:30:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/1/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-01-2020 17:30:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP9DRG	Initial Entry

**5.a Sample ID**

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-01-2020 17:30:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9DRG	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-01-2020 16:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-01-2020 16:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-01-2020 16:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-01-2020 16:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/1/2020 14:15	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-01-2020 16:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-01-2020 16:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**7. Route:**

Date	Location	User	Value	Reason
Sep-01-2020 16:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-01-2020 16:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

**11. Was the subject observed for at least the protocol specified observation period after investigational product administration?**

Date	Location	User	Value	Reason
Sep-01-2020 16:34:05 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Oct-01-2020 16:46:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-01-2020 16:34:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Oct-01-2020 16:34:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Transcription Error
Sep-23-2020 15:54:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 10:08:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The visit was not performed, the entry was wrong. On 22/Sep/2020 the subject came to COVID ILLNESS VISIT.
Sep-23-2020 05:21:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this visit.
Sep-22-2020 16:44:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Erroneous Visit is marked, but date of visit is entered. Please check whether other assessments are performed at this

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

				visit.
Sep-22-2020 16:44:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Oct-01-2020 16:46:23 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Sep-22-2020 16:44:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Buenos Aires		(b) (4), (b) (6)	Symptom::  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	FAT IG UE NO
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2.b Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom::  Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	HEA DA CHE NO

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.c Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <u>Symptom::</u> CH ILL S  <u>Were fever or systemic symp</u> NO <u>toms present on the last day t</u> <u>he Subject Diary was comple</u> <u>ted?:</u>	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.e

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.f Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSEN ED MUSC LE PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

2.g Symptom:

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENERED JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

**2.h Symptom:**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT PAI N	Initial Entry

**2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Injection Site Location:**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**4. Injection Site Body Side:**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS <b>Were injection site reactions NO</b> <b>present on the last day the S</b> <b>ubject Diary was completed</b> <b>?:</b>	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.c

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> PAIN A T INJE CTION SITE  <b>Were injection site react NO ions present on the last day the Subject Diary w as completed?:</b>	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-01-2020 16:49:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Sep-30-2020 18:12:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-30-2020 18:12:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-02-2020 11:16:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-01-2020 16:51:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	information updated
Oct-01-2020 16:33:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinquery: If subject received both doses please update EoT at Visit 3 and disposition status as completed
Sep-30-2020 18:12:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-30-2020 18:12:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Sep-30-2020 18:12:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/30/2020	Initial Entry
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5.a

Date	Location	User	Value	Reason
Sep-30-2020 18:12:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP7XM6	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 18:12:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP7XM6	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-30-2020 18:12:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLC0HT	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 18:12:21 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLC0HT	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-30-2020 18:12:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BLC0HS	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

		(b) (4), (b) (6)		
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**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-30-2020 18:12:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BLC0HS	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History  
Sep/22/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda**Subject No:** 12261094**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Sep-22-2020 16:52:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-22-2020 16:45:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Sep-22-2020 16:45:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Sep-22-2020 16:45:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Sep-22-2020 16:45:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/16/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Nov-12-2020 07:47:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	conva visit completed
Nov-07-2020 13:12:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	keep in candidate state until the visit is entered
Nov-07-2020 08:39:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The subject did not come on the scheduled date. The site is in contact to reschedule the visit that will be updated as soon as the subject comes.
Nov-06-2020 10:35:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Corresponding Convalescent Visit is not yet initiated, please review and update appropriately.
Nov-02-2020 04:06:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	DM: To be followed up later in week as per site response.

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261094**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54

Nov-01-2020 12:55:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	scheduled to 04nov2020
Oct-31-2020 15:46:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Subject has completed illness Visit and symptoms are resolved, however corresponding Convalescent Visit not yet initiated. Please review and update as appropriate. Thank you.
Oct-01-2020 16:49:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Sep/29/2020	New Information
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: FEVER Symptom Present: NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

4.b

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261094**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54**4.c Symptoms:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

**4.d Symptoms:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Symptom Present: NO	
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4.e Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom P</b> NO <b>resent:</b>	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.g

Date	Location	User	Value	Reason

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASE : D SORE THROAT <b>Symptom</b> NO <b>Present:</b>	Initial Entry
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4.g Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.i

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> YES	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**7. Test Result:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Sep-22-2020 16:49:24 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261094**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-22-2020 16:51:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-22-2020 16:51:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-23-2020 10:06:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-22-2020 16:51:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Sep-22-2020 16:51:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Sep-23-2020 10:06:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> The nasal swab was performed on site. The barcode is attached on "SW	Initial Entry



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

(b) (4), (b) (6) AB PFE" item.

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261094**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-22-2020 16:52:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-22-2020 16:52:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-22-2020 16:52:39 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/22/2020	New Information
Sep-22-2020 16:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 16:52:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 16:52:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-22-2020 16:52:14 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Buenos Aires

(b) (4), (b) (6)

**Sample ID:** BP7X7C

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-22-2020 16:52:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP7X7C	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Sep/22/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIAL IST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENC Y ROOM <b>Occurrence of Visit s or Contacts:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Sep/22/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda**Subject No:** 12261094**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

***1.d***

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Sep/22/2020

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE C ONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History Sep/22/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

***1.e Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

***1.e Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.f***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

***1.f Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
Sep-22-2020 16:55:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Sep-22-2020 16:55:25 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History  
Sep/22/2020

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

			<b>Lab Normal Range:</b> Not Applicable	
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Buenos Aires	(b) (4), (b) (6)	<b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test:</b> Not Applicable <b>Result:</b> Not Applicable <b>Not Done:</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable
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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.c Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.d

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry



Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.d Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.e Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.f

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.f Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.g Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Sep-22-2020 16:56:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
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5.a

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF  
Sep/22/2020 Audit Trail History

Form Version: 30-Jul-2020 21:28

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Servicos Medicos Ltda

Subject No: 12261094

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			<b>Lab Normal Range:</b> Not Applicable	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Buenos Aires	(b) (4), (b) (6)	<b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test:</b> Not Applicable <b>Result:</b> Not Applicable <b>Not Done:</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable
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Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

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Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

5.b Sponsor ID:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.b Result:

Date	Location	User	Value	Reason
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5.b Not Done:

Date	Location	User	Value	Reason
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5.b LNMT

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

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Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

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Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Result::	Not Applicable
			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.c Sponsor ID:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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5.c Not Done:

Date	Location	User	Value	Reason
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5.c LNMT

Date	Location	User	Value	Reason
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5.d

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

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**Subject No:** 12261094

**Subject Initials:** ---

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Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

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Generated Time (GMT): 29-Mar-2021 13:54

5.d Sponsor ID:

Date	Location	User	Value	Reason
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5.d Test:

Date	Location	User	Value	Reason
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Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

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Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

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			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

5.e Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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Date	Location	User	Value	Reason
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5.f

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

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Sep/22/2020 Audit Trail History

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5.f Sponsor ID:

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5.f Test:

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Date	Location	User	Value	Reason
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5.f LNMT

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5.g

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

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Subject No: 12261094

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 13:54

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			Not Done::	Not Applicable
			Lab Normal Range:	Not Applicable

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Date	Location	User	Value	Reason
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5.g LNMT

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5.h

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

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**Form Version:** 30-Jul-2020 21:28

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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Form Version: 30-Jul-2020 21:28

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Generated Time (GMT): 29-Mar-2021 13:54

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5.h LNMT

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5.i

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Version:** 30-Jul-2020 21:28

**Form Status:** Data Complete, Frozen, Verified

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**Subject No:** 12261094

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**Generated Time (GMT):** 29-Mar-2021 13:54

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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

5.i Sponsor ID:

Date	Location	User	Value	Reason
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5.i LNMT

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Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			<b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	
--	--	--	---	--

5.j Sponsor ID:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Sep-22-2020 16:57:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:**

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History  
Sep/22/2020

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**I. Date:**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 10 7 <b>Diastolic::</b> 67 <b>Respiratory Rate in respiratio</b> 16 <b>ns/minute:</b> <b>Heart Rate in beats/minute:</b> 79	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 107	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 67	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:27

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 16	Initial Entry

*2.a Heart Rate in beats/minute:*

Date	Location	User	Value	Reason
Sep-22-2020 16:58:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 79	Initial Entry



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail  
Sep/22/2020

**Form Version:** 30-Jul-2020 21:28

**Form Status:**

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Date	Location	User	Value	Reason
Sep-22-2020 16:58:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History  
Sep/22/2020

Form Version: 30-Jul-2020 21:28

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**I. Date:**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Oxygen Saturation:</b> 97.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.0	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Sep-22-2020 16:58:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Sep-22-2020 16:59:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Sep-22-2020 16:59:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Sep-22-2020 16:59:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Sep-22-2020 16:59:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Sep-22-2020 16:59:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/22/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Sep-22-2020 16:59:19 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History  
Sep/22/2020

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Sep-22-2020 16:59:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Sep-22-2020 16:59:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Sep-22-2020 16:59:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Sep-22-2020 16:59:37 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Dec-18-2020 05:23:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Closed as data entered.
Dec-17-2020 17:45:14 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	completed
Dec-17-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-17-2020 10:17:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Microbiology Specimen form' at this visit. Thank you.
Dec-17-2020 10:12:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Dec-16-2020 17:38:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-16-2020 17:38:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

				Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-16-2020 17:38:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) ( )	<b>Data Entry:</b> Dec/15/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Dec-16-2020 17:38:59 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_B	Initial Entry



Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/15/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/9/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Dec/15/2020	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: FEVER Symptom Present: NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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4.b

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH <b>Symptom Present:</b> NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SHORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1226**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda**Subject No:** 12261094**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 13:54**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.d**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHILLS <b>Symptom Present:</b> NO	Initial Entry

**4.d Symptoms:**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

**4.d Was symptom present?**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

			Symptom Present:	NO
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4.e Symptoms:

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW OR INCREASE : D SORE THROAT Symptom NO Present:	Initial Entry
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4.g Symptoms:

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: DIARRHEA Symptom Present: YES	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.i

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Dec-16-2020 17:39:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

**7. Test Result:**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-17-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-17-2020 17:44:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Dec/15/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Dec-17-2020 17:44:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> RW90986	Initial Entry

**5.a Sample ID**

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Dec-17-2020 17:44:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RW90986	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Dec-17-2020 17:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-17-2020 17:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-17-2020 17:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

Date	Location	User	Value	Reason
Dec-17-2020 17:45:00 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SELF SWAB	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Dec/15/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: Unkn wn Occurrence of Visits or Contacts: NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: Unkn wn Occurrence of Visits or Contacts:	Initial Entry
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: Unkn wn Occurrence of Visits or Contacts: Unkn wn	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-18-2020 17:27:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clos ed	Auto closed by Validation Check: VC_HOHCU002_01
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-18-2020 12:59:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6486447;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unknown <b>Occurrence of Visits or Contacts:</b> YES Number of Visits or Contacts: 1	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unknown	Initial Entry
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unknown	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

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Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-18-2020 17:27:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clos ed	Auto closed by Validation Check: VC_HOHCU002_01
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Initial Entry
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Num ber o f Visi ts or Cont acts:</i>  1	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-18-2020 12:59:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6486468;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unkno wn	Initial Entry
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*I.c*

Date	Location	User	Value	Reason
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b>	Initial Entry
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b> Unkno wn	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

***I.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

***I.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-18-2020 17:27:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clos ed	Auto closed by Validation Check: VC_HOHCU002_01
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Initial Entry
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-18-2020 12:59:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6486469;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unkno wn	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

*I.d*

Date	Location	User	Value	Reason
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b>	Initial Entry
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b> Unkno wn	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

***1.d Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

***1.d Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-18-2020 17:27:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_HOHCU002_01
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-18-2020 12:59:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6486470;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

*I.e*

Date	Location	User	Value	Reason
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b>	Initial Entry
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b> Unkno wn	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

*I.e Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

*I.e Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-18-2020 17:27:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clos ed	Auto closed by Validation Check: VC_HOHCU002_01
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Initial Entry
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-18-2020 12:59:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Ope ned	DMW6486471;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unkno wn	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*If*

Date	Location	User	Value	Reason
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b>	Initial Entry
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> Unkno wn <b>Occurrence of Visits or Contacts:</b> Unkno wn	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

*If Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

*If Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Dec-18-2020 17:27:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Clo sed	Auto closed by Validation Check: VC_HOHCU002_01
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ans wered	Initial Entry
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> :	Initial Entry
Dec-18-2020 12:59:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW6486472;Occurrence of Visits or Contacts is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_ILL 2 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry
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2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unknown	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Dec-18-2020 17:27:53 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_HOHC002_02
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Dec-18-2020 14:02:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
Dec-18-2020 14:01:52 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-18-2020 12:59:31	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Open	DMW6486534;Response to 'Has the subject been

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

(UTC-03:00) City of Buenos Aires			ned	hospitalized due to potential COVID-19 illness?' is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify
Dec-16-2020 17:44:20 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unkn wn	Initial Entry

**Header Text:** C4591001

**Visit:** POT\_COVID\_ILL 2 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
Dec/15/2020

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-23-2020 09:04:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Dec-23-2020 09:04:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-23-2020 09:04:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Nov/11/2020

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Date of Visit**

Date	Location	User	Value	Reason
Nov-11-2020 14:07:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/11/2020	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Nov-11-2020 14:07:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/11/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1226**Subject No:** 12261094**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 13:54[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-11-2020 17:55:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-11-2020 17:55:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-11-2020 17:55:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-11-2020 17:55:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-11-2020 17:55:36 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Nov/11/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-11-2020 17:55:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR697H	Initial Entry

**5.a Sample ID**

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Nov/11/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Nov-11-2020 17:55:44 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR697H	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Nov-11-2020 17:55:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS2XK0	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-11-2020 17:55:56 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS2XK0	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-11-2020 17:56:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS2XJZ	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Nov-11-2020 17:56:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS2XJZ	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled Visit on Feb/04/2021

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-05-2021 08:04:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/4/2021	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Feb-05-2021 08:04:02 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_B1	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Feb/04/2021

Form Version: 22-Apr-2020 21:03

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-05-2021 09:28:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-05-2021 09:28:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-05-2021 09:28:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-05-2021 09:28:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-05-2021 09:28:12 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Feb/4/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-05-2021 09:28:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR6867	Initial Entry

**5.a Sample ID**

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** POT\_COVID\_CONVA 2 - Unscheduled  
Visit on Feb/04/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Feb-05-2021 09:28:22 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR6867	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-05-2021 09:28:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSCW48	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 09:28:33 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCW48	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-05-2021 09:29:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BSCW47	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-05-2021 09:29:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSCW47	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** End of Treatment - Unscheduled

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-01-2020 16:34:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-01-2020 16:34:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-01-2020 16:34:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-11-2021 11:24:49 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/19/2021	Initial Entry

**Header Text:** C4591001

**Visit:** Potential ReVax Initial Contact -  
Unscheduled

**Form Version:** 10-Dec-2020 02:25

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail  
History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**I. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Mar-11-2021 11:28:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 11:25:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Mar-11-2021 11:25:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for V accination 3 Participant is:  eligible per local/national recom mendations and confirmed to hav e received only placebo at Vacc ination 1/2	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-11-2021 11:25:29 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/11/2021	Initial Entry

Header Text: C4591001

Visit: V101\_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

I. Consent Was:

Date	Location	User	Value	Reason
Mar-12-2021 13:55:54 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-12-2021 07:34:07 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject signed the Informed Consent on 04FEB2021 during COVID_B1 visit (COV CONV)
Mar-11-2021 18:47:28 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7679281;Date Written Consent Obtained in the Informed Consent - Further Vaccination CRF should be equal to or after Date Treatment Unblinded on the Treatment Unblinded CRF. Please review and update as appropriate.
Mar-11-2021 16:54:40 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 1: Closed	Response satisfies query
Mar-11-2021 11:37:18 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the term was signed at the COV CONV
Mar-11-2021 11:31:11 (UTC-03:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date Informed Consent Obtained is not the same as the

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

City of Buenos Aires				Date of Visit. Please correct as necessary.
Mar-11-2021 11:31:11 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> OBTAINED Date Written Consent Obtained  Feb/4/2021	Initial Entry

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/11/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:13 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:14

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/11/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 113	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

			<b>d Identifier:</b> <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	
--	--	--	--	--

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Mar-11-2021 11:26:42 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Mar-12-2021 07:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-12-2021 07:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-12-2021 07:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-12-2021 07:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-12-2021 07:22:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Mar/11/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-12-2021 07:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRGZ3L	Initial Entry

**5.a Sample ID**

090177e196ae404f\Final\On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Mar-12-2021 07:23:47 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRGZ3L	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-12-2021 07:24:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRXW7T</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 07:24:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXW7T	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-12-2021 07:25:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BRXW7V</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-12-2021 07:25:08 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BRXW7V	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Mar-11-2021 16:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-11-2021 16:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-11-2021 16:42:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 16:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-11-2021 16:41:48 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Mar/11/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-11-2021 16:42:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BRGZ4D	Initial Entry

**5.a Sample ID**

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1226

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e  
Servicos Medicos Ltda

**Subject No:** 12261094

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 13:54

Date	Location	User	Value	Reason
Mar-11-2021 16:42:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRGZ4D	Initial Entry

Header Text: C4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/11/2021 10:10	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: V101\_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1226

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject No: 12261094

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 13:54

7. Route:

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Mar-11-2021 11:27:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	



**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4)	Form Created	

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-19-2021 14:13:01 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Closed	Thank you for your prompt response.
Jan-15-2021 11:19:43 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	A FUP was sent with new information.
Jan-15-2021 11:11:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 2: Reissued: Opened	Thanks for confirming. Please make every effort possible to obtain further information and respond to the query once additional information is available.
Jan-11-2021 14:52:09 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	A FUP will be sent soon.
Jan-10-2021 13:39:03	ACV0PFEINFP6000	Giselle Castillo	Query 2: Opened	Per report, the subject presented

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

(UTC-03:00) City of Buenos Aires		(b) (4)		with "fever and chills". Kindly clarify, was this was a complicated case of Nephrolithiasis with infection?. Please provide further relevant test (including imaging) in a FU form. thank you.
Jan-07-2021 18:01:06 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Closed	Discrepancy has been closed.
Jan-07-2021 16:38:58 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Worsening of Nephrolithiasis	New Information
Jan-06-2021 15:04:35 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Would you Please consider unlock Medical History Page so we can add "Nephrolithiasis". Thanks
Jan-06-2021 12:06:30 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 1: Opened	Multiple concepts in the term RIGHT URETRAL OBSTRUCTION DUE TO KIDNEY STONES. Split the term into RIGHT URETERAL OBSTRUCTION and KIDNEY STONES and submit separately. Thank you.
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Right Uretral Obstruction Due to Kidney Stones	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-13-2021 14:51:16 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/21/2020 UNK:UNK	New Information
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/30/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-26-2021 16:37:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Jan/22/2021 UNK:UNK	New Information
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-08-2021 06:34:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 16:38:58 (UTC-03:00) City of	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Worsening of Nephrolithiasis:

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Buenos Aires				Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Right Uretral Obstruction Due to Kidney Stones: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p>	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

			NO	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Nephrolithiasis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-26-2021 16:37:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Jan-26-2021 16:37:51 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Jan-26-2021 16:37:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Worsening of Nephrolithiasis: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE End Date/Time is present.
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-06-2021 08:54:31 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Jan-08-2021 06:34:45 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021006926	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Urinary tract infection	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/29/2020 UNK:UNK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Jan/5/2021 UNK:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
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090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)



Header Text: C4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1226

Subject No: 12261094

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 13:54

Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry
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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  If Other, specify:  Worsening of nephrolithiasis	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Logs - Unscheduled

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Status:** Data Complete, Locked, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jan-13-2021 14:56:41 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Disposition - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Mar-11-2021 11:28:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/20/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Mar-11-2021 11:28:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDI TIONAL VACCINATION	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Oct-01-2020 16:34:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-12-2020 08:15:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-12-2020 08:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Dec-18-2020 04:22:34 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Dec-17-2020 10:17:15 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Visit made on 15Dec2020.
Dec-15-2020 16:26:03 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 10DEC2020. But there is no COVID Illness visit reported in the database. Please clarify.
Oct-01-2020 16:34:32 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/30/2020	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Subject Status - Unscheduled

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

Aug-12-2020 08:15:10 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/11/2020	Initial Entry
Aug-12-2020 08:13:17 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/11/2020	Initial Entry

090177e196ae404f\Final\Final On: 01-Apr-2021 05:36 (GMT)

**Header Text:** C4591001

**Visit:** Investigator Signature - Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1226

**Subject No:** 12261094

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1226) CEPIC - Centro Paulista de Investigacao Clinica e Servicos Medicos Ltda

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 13:54

[Back to Form](#)

*I. Casebook Signature*

Date	Location	User	Value	Reason
Sep-14-2020 16:35:26 (UTC-03:00) City of Buenos Aires	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry